

## DYNAMIC HEALTH ASSESSMENTS FOR MEDICAL REHABILITATION OUTCOME

RELEASE DATE: August 21, 2002

RFA: HD-02-024

National Institute of Child Health and Human Development (NICHD)  
(<http://www.nichd.nih.gov>)

National Eye Institute (NEI)  
(<http://www.nei.nih.gov>)

LETTER OF INTENT RECEIPT DATE: February 11, 2003

APPLICATION RECEIPT DATE: March 11, 2003

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### PURPOSE OF THIS RFA

The National Center for Medical Rehabilitation Research (NCMRR) at the National Institute of Child Health and Human Development (NICHD) and the National Eye Institute (NEI) seek to fund health assessment research focused on disability concepts such as quality of life, health, functional and social interaction status for persons with disabilities. The goal of this Request for Applications (RFA) is to encourage multidisciplinary research on the measurement of the health of persons with disabilities utilizing techniques such as computer adaptive testing or simulations to improve the quality and scientific power of data. The planning grants invited through this RFA will

provide a mechanism for early peer review of the rationale and design of the potential health assessments and collaborations, and will provide successful applicants with resources to assist in development of detailed health assessments. This approach may be useful in developing an assessment tool that could be used to diagnose or to document the impact of a rehabilitation intervention. This approach may result in a tool for better evaluating medical interventions at the impairment level and also lead to better understanding of the relationship between health challenges and disability concepts for individuals in widely differing circumstances.

The purpose of the planning grant is to obtain detailed information on specific aspects of the proposed research. This may include organizing an effective research group, developing a theoretical perspective, utilizing a unique methodological approach and identifying or devising appropriate instruments. Involvement of representatives from the targeted patient populations in planning and conducting the research effort is highly recommended. A phase II initiative is anticipated that will implement the dynamic health assessment instrument in populations of interest.

## RESEARCH OBJECTIVES

### Background

Millions of people in the United States suffer disabling injuries or diseases each year. Over 50 million individuals live with chronic physical impairments and disabilities due to conditions such as cerebral palsy, metabolic disorders, burns, arthritis, etc. For individuals with disabilities, the process of rehabilitation may begin with acute illness and continue through integration into the community. Thus, this population is a valuable resource in understanding the relationship between the nature of a health condition and the role of environmental and social interactions in their health status. However, there is a dearth of measures that are responsive and sensitive enough to track changes in disability from inpatient rehabilitation to community participation or from pathophysiology to community participation

### Research Scope

With the increasing population of persons with disabilities, advances in computer science, proliferation of new medical and treatment interventions, and availability of a variety of outcome measures, there is a need as well as a capacity for developing an efficient health assessment. One of the major goals of the rehabilitation intervention is to improve the independence and quality of life of the individual. An important challenge is to develop instruments to measure these and other improvements in a valid and reliable way. To accomplish this task, an instrument should incorporate advances in

areas such as: self-reports, research design, measurement techniques, data collection processes and analytic methods.

Multidisciplinary approaches are strongly encouraged. Potential applicants are urged to explore the ideas and methods developed in social science and behavioral fields other than their own. Consulting relevant literature and collaborating with colleagues from other disciplines may provide important opportunities for cross-fertilization in developing improved methodology and measurement.

Potential applicants specifically concerned with research regarding the social and cultural dimensions of health should view two conference proceedings:

In June 2000, the Office of Behavioral and Social Sciences Research held a conference, "Toward Higher Levels of Analysis: Progress and Promise in Research on Social and Cultural Dimensions of Health." In an agenda-setting activity that followed the conference, a panel of scientists developed an ambitious research agenda on the social and cultural dimensions of health. A program announcement based on the panel's recommendations for substantive research has been issued by the OBSSR and can be found at: <http://grants.nih.gov/grants/guide/pa-files/PA-02-043.html>. However, the research agenda also included detailed recommendations relating to needed methodological research related to the social and cultural dimensions of health. Potential applicants are encouraged to consult this report, available at [http://obssr.od.nih.gov/Conf\\_Wkshp/higherlevel/conference.html](http://obssr.od.nih.gov/Conf_Wkshp/higherlevel/conference.html).

In September 2001, NIH sponsored an International Conference entitled "Stigma and Global Health: Developing a Research Agenda." Among the recommendations was to encourage research intended to develop methodological, evaluative, and analytic tools for 1) studying stigma and its consequences with respect to health and 2) development, evaluation, and optimization of interventions to prevent or mitigate the negative effects of stigma and discrimination on health. In both areas it was recommended that the social and cultural dimensions of stigma and its manifestations be included. Applicants are encouraged to refer to the stigma conference website (<http://www.stigmaconference.nih.gov>) for further resources and information.

Some examples of the topics that might be addressed in an application responsive to this RFA are listed below:

- o Processes Underlying Self-Report
- o Processes Underlying Observation Measures
- o Research Design
- o Measurement Issues
- o Data Collection Techniques

- o Analytic Methods
- o Data Display

(1) PROCESSES UNDERLYING SELF-REPORTS: Issues related to self-reports that need to be taken into consideration are: comprehension of questions; retrieval of information from memory; and use of heuristics and prior beliefs in formulating responses. These may not only influence how one responds to the question, but which individuals with disabilities may be able to respond.

(2) PROCESSES UNDERLYING OBSERVATION MEASURES: The rehabilitation health professional is called upon to make subjective observations concerning the progress of individuals receiving interventions. Continued improvement and innovation in gathering clinical interview information and observational methods is needed to understand how various methods work in diverse rehabilitation populations and how they can be modified to address specific needs of individuals. Techniques for validating and replicating findings from qualitative research, including collection strategies, development of coding protocols, and techniques that facilitate the integration and validation of qualitative and quantitative measurement.

(3) RESEARCH DESIGN: Research design determines to a large extent how well a research plan can accomplish stated purposes and test hypotheses. As a result, the application should address the pilot sampling plan: selection of appropriate study designs, methods, procedures, and measures, to assure confidence in the study's internal and external validity. In addition, methods for archiving and disseminating complex datasets, especially longitudinal datasets on individuals with disabilities, in ways that protect identifiers of study participants so that the datasets can be used by investigators who were not part of the original research team.

(4) MEASUREMENT ISSUES: The dimensions covered and the depth of coverage must be appropriate for specific rehabilitation patients in whom they are applied. Ceiling and floor effects can occur when an instrument or certain scales of an instrument are used for a group of individuals who have much better or worse function than the scales are designed to measure. Balancing the length of the instrument to solicit sufficient information in any particular content area, but not increase the burden on the respondent is another issue to consider. How to combine existing measures into a comprehensive measure is also a challenge. Use of the instrument to provide individual status versus group status is another area to consider.

(5) DATA COLLECTION TECHNIQUES: Innovative methodologies for data collection can result in the collection of new or more complex types of data by rehabilitation health professionals. Recent developments in computer-assisted testing have permitted more complex question sequences as well as

web-based data collection. Utilizing virtual environments to simulate consistent environments is another potential innovation. In addition, the development of hand-held beepers programmed for data entry has permitted the collection of time-specific data. How these or other advances will be used with individuals with disabilities should be addressed.

(6) ANALYTIC METHODS: The goal of new and improved analytic methods is to help make estimation, hypothesis testing, and causal modeling based upon scientific data as sound as possible. Challenges include developing techniques that distinguish underlying regularities from the 'noise' created by variability and imprecise measurement, and developing appropriate analytic techniques for use with new kinds of data and new approaches to rehabilitation research.

(7) DATA DISPLAY: Making the results of the health assessment useful to clinicians is another goal. One approach to this is to provide graphic or other display of data that is interpretable to clinicians.

#### MECHANISM OF SUPPORT

This RFA will use NIH Exploratory/Development Grant (R21) award mechanism. As an applicant you will be solely responsible for planning, directing, and executing the proposed project. This RFA is a one-time solicitation. The anticipated award date is December 2003.

The R21 mechanism is to be used for support of creative, novel, and/or high risk/high payoff approaches that could produce innovative advances in this field. The R21 provides the means to acquire the necessary pilot information, to attract talented new investigators, to carry out feasibility studies and protocol planning, to incorporate new concepts from related disciplines, and to foster the development of interdisciplinary, inter-institutional collaborative efforts among investigators with diverse training and expertise. These grants are non-renewable, and may not be used to supplement an ongoing grant.

This RFA uses just-in-time concepts. It also uses the modular budgeting format (see <http://grants.nih.gov/grants/funding/modular/modular.htm>). Specifically, if you are submitting an application with direct costs in each year of \$250,000 or less, use the modular format.

#### FUNDS AVAILABLE

The participating institutes intend to commit approximately \$1.5 million (NICHD \$1 million and NEI \$500,000) in total costs [Direct plus Facilities and Administrative (F&A) costs] in FY 2003 to fund up to 10 new grants in response to this RFA. An applicant for an R21 may request a project period

of up to three years and a budget of \$100,000 per year in direct costs. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the NICHD and NEI provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

## ELIGIBLE INSTITUTIONS

You may submit an application if your institution has any of the following characteristics:

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories
- o Units of State and local governments
- o Domestic or foreign
- o Faith-based organizations

## INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

## SPECIAL REQUIREMENTS

Applicants will be expected to budget one meeting of funded Principal Investigators in the Washington DC area each year.

## WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

- o Direct your questions about scientific/research issues to:

Louis Quatrano, Ph.D.  
Behavioral Sciences and Rehabilitation Engineering  
National Institute of Child Health and Human Development  
6100 Executive Boulevard, Room 2A03, MSC 7510

Bethesda, MD 20892-7510  
Telephone: 301-402-4221  
FAX: 301-496-0832  
E-mail: [quatranl@exchange.nih.gov](mailto:quatranl@exchange.nih.gov)

Maryann Redford, D.D.S., MPH  
Director, Collaborative Clinical Research  
National Eye Institute  
Executive Plaza South,  
6120 Executive Boulevard, Suite 350, MSC 7164  
Bethesda MD 20892-7164  
Telephone: 301-451-2020  
FAX: 301-402-0528  
Email: [maryann.redford@nei.nih.gov](mailto:maryann.redford@nei.nih.gov)

o Direct your questions about peer review issues to:

Robert H. Stretch, Ph.D.  
Director, Division of Scientific Review  
National Institute of Child Health and Human Development  
6100 Executive Boulevard, Room 5B01, MSC 7510  
Bethesda, MD 20892-7510  
Telephone: 301-496-1485  
FAX: 301-402-4104  
Email: [stretchr@nih.gov](mailto:stretchr@nih.gov)

o Direct your questions about financial or grants management matters to:

Christopher Myers  
Grants Management Branch  
National Institute of Child Health and Human Development  
6100 Executive Boulevard, Room 8A17, MSC 7510  
Telephone: 301-435-6996  
FAX: 301-402-0915  
Email: [cm143g@nih.gov](mailto:cm143g@nih.gov)

William W. Darby  
Grants Management Officer  
National Eye Institute  
6120 Executive Boulevard, Suite 350, MSC 7164  
Bethesda MD 20892-7164  
Telephone: 301-451-2020  
FAX: 301-496-9997  
Email: [wwd@nei.nih.gov](mailto:wwd@nei.nih.gov)

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

- o Descriptive title of the proposed research
- o Name, address, and telephone number of the Principal Investigator
- o Names of other key personnel
- o participating institutions
- o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NICHD staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to:

Louis Quatrano, Ph.D.  
Behavioral Sciences and Rehabilitation Engineering  
National Institute of Child Health and Human Development  
6100 Executive Boulevard, Room 2A03, MSC 7510  
Bethesda, MD 20892-7510  
Telephone: 301-402-4221  
FAX: 301-496-0832  
Email: [quatrani@exchange.nih.gov](mailto:quatrani@exchange.nih.gov)

#### SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).

**SUPPLEMENTAL INSTRUCTIONS:** The Research Plan for the R21 application need not include preliminary data and should be limited to 15 pages. Appendices may not be submitted.

#### SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS:

Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular grant format. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in \$25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at

<http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

**USING THE RFA LABEL:** The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: <http://grants.nih.gov/grants/funding/phs398/label-bk.pdf>.

**SENDING AN APPLICATION TO THE NIH:** Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Center for Scientific Review  
National Institutes of Health  
6701 Rockledge Drive, Room 1040, MSC 7710  
Bethesda, MD 20892-7710  
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must be sent to:

Robert H. Stretch, Ph.D.  
Director, Division of Scientific Review  
National Institute of Child Health and Human Development  
6100 Executive Boulevard, Room 5B01, MSC 7510  
Bethesda, MD 20892-7510  
Rockville, MD 20852 (for express/courier service)

**APPLICATION PROCESSING:** Applications must be received by the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an Introduction addressing the previous critique.

## PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NICHD and NEI. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NICHD in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

- o Receive a written critique
- o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score
- o Receive a second level review by the NICHD National Advisory Council or Board.

## REVIEW CRITERIA

The NIH R21 "planning grant" is a mechanism for supporting exploratory development projects that can realistically be expected to be completed in three years and that require only a modest level of funding. Because this is a planning grant, the application will not have the same level of detail or extensive discussion found in an R01 application. Accordingly, reviewers should evaluate the conceptual framework and general approach to the problem, placing less emphasis on methodological details and certain indicators traditionally used in evaluating the scientific merit of R01 applications (e.g., hypothesis-driven design, supportive preliminary data).

In the written comments, reviewers will be asked to discuss the following aspects of your application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment

The scientific review group will address and consider each of these criteria in assigning your application's overall score, weighting them as appropriate for each application. Your application does not need to be strong in all categories to be judged likely to have major scientific impact and thus

deserve a high priority score. For example, you may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) **SIGNIFICANCE:** Scientific significance of the proposed assessment, including analysis of the need and potential impact on health care, comparison with competitive assessments, and relevance of the proposed assessment to rehabilitation outcomes desired by the target patient population.

(2) **APPROACH:** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Do you acknowledge potential problem areas and consider alternative tactics? Is there an adequate basis for the project in relevant literature?

(3) **INNOVATION:** What is the potential of the proposed planning activity to lead to a reliable and valid assessment that is briefer, more flexible, more efficient, and a more precise assessment than conventional methods? Does your project employ novel concepts, approaches or methods? Are the aims original and innovative? Does your project challenge existing paradigms or develop new methodologies or technologies?

(4) **INVESTIGATOR:** Qualifications and research experience of the principal investigator in developing assessments, and for instrument development, a group of multidisciplinary investigators, and a clear statement of the leadership and proposed organization of the assessment team.

(5) **ENVIRONMENT:** Does the scientific environment in which the work will be done contribute to the potential of the proposed planning activity to establish necessary collaborative linkages, and the capacity of the group to analyze data and prepare clinically relevant reports?

#### ADDITIONAL REVIEW CRITERIA

In addition to the above criteria, your application will also be reviewed with respect to the following:

o **PROTECTIONS:** The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

o **INCLUSION:** The adequacy of plans to include subjects from genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below.)

- o DATA SHARING: The adequacy of the proposed plan to share data.
- o BUDGET: The reasonableness of the requested budget and period of support in relation to the proposed research.

#### RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: February 11, 2003  
Application Receipt Date: March 11, 2003  
Peer Review Date: June/July 2003  
Council Review: September/October 2003  
Earliest Anticipated Start Date: December 1, 2003

#### AWARD CRITERIA

Criteria that will be used to make award decisions include:

- o scientific merit (as determined by peer review)
- o Availability of funds
- o Programmatic priorities.

#### REQUIRED FEDERAL CITATIONS

**INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH:** It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a)

all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

#### **INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:**

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at <http://grants.nih.gov/grants/funding/children/children.htm>.

#### **REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH**

policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

#### **PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The**

Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at [http://grants.nih.gov/grants/policy/a110/a110\\_guidance\\_dec1999.htm](http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm).

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure

informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

**URLs IN NIH GRANT APPLICATIONS OR APPENDICES:** All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

**HEALTHY PEOPLE 2010:** The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

**AUTHORITY AND REGULATIONS:** This program is described in the Catalog of Federal Domestic Assistance Nos. 93.929, and 93.867 and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies described at <http://grants.nih.gov/grants/policy/policy.htm> and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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